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Ethics Oversight in Conflict Research: Why Some Studies in Darfur Were Conducted Without Approval – Insights from a Qualitative Investigation

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Abstract

Armed conflicts involve numerous challenges that make it more difficult to adhere to standard research ethics compared to studies conducted during peacetime. A qualitative study was conducted to explore the factors influencing the reporting of ethical approval in published research, using studies carried out by humanitarian agencies in Darfur, western Sudan, between 2004 and 2012 as a case example. The study employed a qualitative approach, utilizing interviews and focus group discussions with key stakeholders, including representatives from national and international NGOs, UN agencies, and Sudan's national humanitarian and research regulatory bodies. The study included 38 participants, comprising 5 interviewees and 33 focus group members. Participants largely agreed on the necessity of ethical oversight for research conducted in humanitarian contexts in Sudan, particularly in Darfur. Through thematic analysis, five key themes emerged to explain why humanitarian studies in Darfur were often not submitted for formal ethical approval: (1) varying definitions of what constitutes research, (2) perceptions that the studies posed minimal risk, (3) the urgency associated with emergency contexts, (4) prior approval of similar studies or research tools, and (5) limited awareness of ethics review procedures. Gaps within institutional humanitarian governance highlight the need for dedicated mechanisms for ethical oversight. The evolving nature of humanitarian crises requires more nuanced approaches to ethics review, underlining the importance of policy measures that align research practices with humanitarian governance and draw lessons from ethics oversight in public health emergencies.

Keywords: Ethics oversight, Conflict, Darfur, Public health emergencies

Introduction

Darfur, in western Sudan, has been embroiled in armed conflict since 2003, with catastrophic consequences for the population. Estimates suggest that the conflict has claimed more than 300,000 lives, displaced over 2.7 million people internally, and left approximately 4.3 million individuals in need of humanitarian assistance [1, 2]. Children have been disproportionately affected, with around 2.5 million under the age of five facing food insecurity. Additionally, millions have sought refuge both within Sudan and across borders in countries such as Chad and Egypt, as well as in parts of Europe [3–8].

Humanitarian interventions by international NGOs and UN agencies have been ongoing since the conflict began, aiming to provide life-saving support including food, shelter, and healthcare. Despite these efforts, aid delivery has been constrained by restricted access to affected areas, safety risks for personnel, limited resources, and inconsistent funding streams [9–12].

The political landscape in Sudan has further shaped the humanitarian environment. The 2019 transition, which saw the removal of President Omar al-Bashir and the formation of a transitional government, initially offered the prospect of stability. However, renewed conflict in April 2023 intensified humanitarian pressures, resulting in nearly 6 million people being displaced internally and over 1.4 million fleeing to neighboring countries by October 2023. The compounded crises strained basic

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resources such as food, water, and fuel, and overwhelmed healthcare systems, creating severe shortages in essential medical supplies.

In this context, research is crucial for understanding the needs of affected populations and improving the impact of humanitarian programs. Studies assessing aid distribution, service gaps, and program effectiveness provide evidence to guide decision-making and inform best practices that can be applied in other humanitarian settings [13].

A prior systematic review [14] evaluated publicly available reports of human research in Darfur between 2004 and 2012, focusing on whether ethical approval and informed consent were reported. The findings indicated that only 13.2% of 68 eligible studies mentioned ethical approval, while 42.6% reported obtaining informed consent. Similarly, none of the 138 reports reviewed from the CRED database indicated ethical approval, and only 12.3% noted informed consent.

Five potential explanations were suggested for these low reporting rates: exemption from ethics review, lack of requirement to report ethics approval, assumption that approval had been granted, use of pre-approved proposals, or omission of ethics reporting from study templates.

Building on these findings, the present study investigates why certain research conducted during the Darfur conflict did not secure formal ethical approval. Using a qualitative approach, we engaged key stakeholders involved in research planning, coordination, and review in Sudan between 2004 and 2012 to explore underlying factors. The studies analyzed were limited to this timeframe, while the qualitative research was carried out in 2018. Publication delays were influenced by multiple factors discussed in the limitations section.

Materials and Methods

Study design

Using focus groups and detailed interviews with key informants, a qualitative study was conducted to understand the underlying causes of the low rates of ethical approval reporting in studies carried out during the Darfur armed conflict.

Sampling and participants' recruitment

Key stakeholders involved in the oversight, coordination, or planning of research and humanitarian activities in Sudan between 2004 and 2012 were selected using a purposive sampling strategy. This method allowed the study to capture insights from individuals with a broad understanding of research governance and humanitarian operations. Targeted participants included representatives from the Humanitarian Aid Commission (HAC), the National Research Ethics Committee (NREC), the Department of Research at the Federal Ministry of Health (FMOH), and international non-governmental organizations (INGOs). Invitations to participate were extended via telephone or through direct visits to participants' offices.

For the purposes of this study, humanitarian agencies are considered organizations that provide aid to populations affected by crises, including armed conflicts and natural disasters. Their work typically involves delivering emergency relief—such as food, shelter, healthcare, and other essential services—to support vulnerable communities. This definition encompasses UN agencies, international NGOs, and local NGOs engaged in humanitarian operations.

Participant inclusion was determined by institutional position rather than direct involvement in specific research projects conducted during the period under review. This approach ensured that participants possessed comprehensive knowledge of research oversight and ethical governance in Darfur, without unnecessarily restricting the participant pool. Direct project involvement was deemed unnecessary, as institutional roles provide sufficient insight into the ethical and technical standards guiding field studies, which are generally consistent across research efforts.

INGOs were specifically selected based on documented research activity in Darfur during the 2004–2012 period [14], ensuring that perspectives were obtained from organizations actively engaged in research relevant to the study's objectives.

Data collection

Semi-structured interviews and focus group discussions (FGDs) were carried out in Khartoum, with interviews conducted at participants' workplaces and FGDs hosted at the Federal Ministry of Health. Both English and Arabic were used during the sessions. Topic guides tailored for this study directed the discussions and interviews. The first author, fluent in both languages, conducted all sessions, which removed the need for real-time translation.

All interviews and FGDs were transcribed by the first author to ensure consistency and accuracy. The process

involved transcribing the discussions in the language they were conducted in, followed by translation into the alternate language if required. To further guarantee data quality, a second author proficient in both languages cross-checked the transcripts, and participants were consulted to validate key sections whenever possible. Any errors or discrepancies identified during these checks were corrected promptly to uphold data integrity. A total of 38 participants were included: 5 individuals in interviews (2 men and 3 women) and 33 in FGDs (19 men and 14 women) **(Table 1).**

Table 1. Number of participants in each category (N = 38)

Participant Category	Number of Invitees	Method	Participants (Total)	Male	Female	Transcription Label
Heads/Directors of Sudan Offices of UN Specialized Agencies and Red Cross/Crescent	6	Interviews	1	1	0	UN
Heads/Directors of Sudan Offices of UN Specialized Agencies and Red Cross/Crescent	5	FGDs	2	1	1	FGD-NGOs
Heads/Directors of Selected INGOs	6	Interviews	1	1	0	INGO
Heads/Directors of Selected INGOs	10	FGDs	8	4	4	FGD-NGOs
Directors of NGOs	20	FGDs	19	13	6	FGD-NGOs
Humanitarian Governance Bodies	3	Interviews	1	0	1	HGB
Research Governance Bodies	–	Interviews	2	1	1	RGB
Relevant FMOH Departments	6	FGDs	4	1	3	FGD-NGOs
Total	56	–	38	22	16	–

FGDs: Focus Group Discussions; FMOH: Federal Ministry of Health (Sudan) (HAC); INGO: International Non-Governmental Organization; NGOs: Non-Governmental Organizations; HGB: Humanitarian Governance Body, which includes the Humanitarian Aid Commission RGB: Research Governance Body, which include the National Research Ethics Committee and the Research department at FMOH; UN: the United Nations NGOs: Non-Governmental Organization;

Data analysis

We conducted a qualitative content analysis using an inductive approach [15, 16]. The transcripts were reviewed multiple times to detect recurring ideas and patterns directly relevant to the study's main question: why some research in Darfur between 2004 and 2012 did not obtain ethical approval.

To organize the analysis, participants were grouped by their institutional affiliations, including government bodies (HAC, FMOH-RD, NREC) and representatives from NGOs and INGOs. This grouping allowed us to examine the perspectives of each category in a focused and systematic manner.

Coding of the transcripts was performed in stages, with repeated iterations to refine categories and uncover major themes. These themes were then analyzed in relation to the research question, and comparisons were made across participant groups to identify convergent and divergent viewpoints.

This inductive process enabled the development of concepts and insights grounded in the data itself, providing a detailed understanding of the contextual factors shaping the ethical oversight of research in Darfur [17].

Data validation

To minimize potential biases in data interpretation [18], we adopted several strategies to enhance the credibility and trustworthiness of our results. We deliberately included a diverse set of participants with varied experiences, ensuring near gender balance across the study sample [19, 20].

Key elements of the research process were integrated to reflect the specific context of Darfur. This included ongoing member checking, where preliminary interpretations, themes, and explanations were shared with participants through online meetings and email exchanges. This iterative feedback allowed us to refine our analyses, verify the accuracy of our findings, and ensure that the results faithfully reflected participants' lived experiences and perspectives.

Ethical considerations

This research was conducted in full alignment with ethical standards, drawing on both the Declaration of

Helsinki [21] and Sudan's National Research Ethics Guidelines [22]. Approval to proceed was obtained from the University of Birmingham Research Ethics Committee and the Sudanese National Research Ethics Committee (NREC).

Verbal consent was obtained from all participants prior to data collection. They were informed that their involvement was voluntary and that they could withdraw at any time before the analysis of their data, with assurance that their contributions would be completely removed if they chose to opt out.

To maintain anonymity, references to participants from research governance bodies (RGB) were generalized to include the Research Directorate at the Federal Ministry of Health, state-level health ministries, and the NREC, without identifying specific individuals. Similarly, descriptions of participants from International Non-Governmental Organizations (INGOs) were kept broad, reflecting the numerous organizations and staff present in Sudan.

Because humanitarian personnel frequently change roles or leave the country, additional precautions were taken to safeguard participants' identities, ensuring confidentiality was preserved throughout the study.

Results and Discussion

The findings are presented under five key themes that emerged from the analysis **(Table 2).** The first theme focuses on the inconsistent understanding of what constitutes research, highlighting the differences in how participants defined and categorized research activities. The second theme examines participants' perceptions of low risk in humanitarian studies, reflecting varying views on the potential harm associated with such work. The third theme addresses the sense of urgency created by the emergency context in Darfur, illustrating how the need for rapid response often took precedence over formal ethical review. The fourth theme considers the role of prior approvals for studies or research tools, revealing practices and assumptions related to pre-existing authorization in humanitarian research. The final theme explores participants' limited knowledge of ethics review procedures, identifying the challenges and obstacles encountered when navigating ethical requirements. Together, these themes provide a detailed picture of the factors shaping decisions about whether to seek formal ethics approval for research conducted in humanitarian settings.

Table 2. Explanations for humanitarian studies in darfur not undergoing formal ethics review

Main Themes	Description
Varying interpretations of research	Differences in how participants defined and classified research activities.
Perceived minimal risk	Divergent views on the level of risk associated with humanitarian studies.
Urgency driven by emergency conditions	The need for rapid response in Darfur often outweighed formal ethical review procedures.
Reliance on prior approvals	Use of previously approved studies or research tools as a basis, reducing the perceived need for new ethics approval.
Limited familiarity with ethics review	Lack of understanding of the procedures and requirements for formal ethics review.

Inconsistent definitions of research

There was considerable variation in how participants understood what qualifies as research, particularly among staff from humanitarian organizations. Many were hesitant to label their work as "research," often describing their data collection activities using alternative terminology. This reluctance was especially pronounced among humanitarian agency personnel, who highlighted the immediate, response-focused nature of their work during crises.

For example, one representative from an international NGO (INGO-1) explained that while their organization conducts formal research in other contexts, in Sudan their activities were primarily rapid assessments aimed at emergency response. When asked directly whether these efforts constituted research, the participant stated, "No. Not research."

By contrast, individuals from research governance bodies emphasized the importance of adhering to standardized definitions of research. They underscored that any study involving human participants falls under recognized research frameworks, such as those outlined by the World Health Organization, which include epidemiological, socio-behavioral, clinical, basic, and socio-economic studies [23, 24].

One governance representative clarified, "[T]he reference definition for research or health research is the same as in the World Health Organization, covering all types—epidemiological, socio-behavioural, basic,

clinical, and socioeconomic… the key criterion is involvement of human participants" (RGB-1).

Perceptions of low-risk

There was a clear divergence in how participants assessed the risk of humanitarian research. Governmental governance representatives generally treated all studies involving human subjects as carrying inherent risks, regardless of context. In contrast, NGO participants often viewed such studies as posing minimal risk, especially when they did not involve biological sampling or direct harm to participants. This led many NGOs to believe that ethical review could be bypassed in cases where potential risks were negligible.

This stance differed markedly from that of government-affiliated governance bodies, which consistently favored a more conservative and cautious approach to evaluating risk in humanitarian research. One NGO participant illustrated this perspective, noting, "[…] where there is no harm and [researchers] do not take biological samples. This can be [an] exception from ethical [review]" (FGD-NGOs2/1).

Perceived urgency due to emergency context

The urgent conditions in Darfur created differing opinions regarding the necessity and timing of ethical approval. NGO representatives highlighted the critical and time-sensitive nature of their work, often describing their interventions as "emergency" or "rapid response" operations. They expressed concern that formal ethical review procedures could slow down their ability to provide immediate assistance. One participant noted, "Any [displacement] camp for us means emergency [operation]," illustrating the pressing nature of their activities. Frustrations were also raised regarding bureaucratic delays in the approval process. As one participant explained, "In Sudan, procedures are very slow. Waiting two months for ratification to work in the Darfur region may mean that what I intended to study has already changed" (FGD-NGOs1/7).

By contrast, representatives from governance bodies challenged the notion of urgency, arguing that the situation no longer justified bypassing ethical oversight. They emphasized that ethics review could be conducted alongside humanitarian operations without hindering aid delivery and stressed the importance of maintaining ethical standards even in high-pressure contexts. UN officials reinforced this perspective, noting that the time required for ethical review could run concurrently with logistical and technical preparations. They cautioned against compromising ethical principles for the sake of speed, underlining the necessity of obtaining informed consent and following established guidelines.

One governance representative stated, "The survey does not take place unless the situation has become somewhat stable, and no one is dying… Ethics review will not disrupt humanitarian aid and will not cause any loss of life" (HGB-1). Another emphasized, "The ethical review committee does not need to take a long time, unlike technical work. I believe it can proceed in parallel. I generally disagree with collecting information in a rush at the expense of consent or ethical standards, because without consent, everything done is unethical. I do not agree with using urgency as an argument" (UN-1).

These contrasting perspectives reveal the tension between the immediate demands of humanitarian response and the obligation to uphold ethical research standards, highlighting the challenges of navigating ethics in emergency settings.

Prior study or tool approval

Several NGO representatives described their partnerships with government ministries as providing an informal form of ethical approval, which they considered sufficient in place of formal review by the National Research Ethics Committee (NREC). Their justification was based on three main arguments. First, government agencies routinely reviewed the data collection instruments used by NGOs, and approval from these authorities was viewed as covering ethical considerations, making additional review by the NREC appear unnecessary. Second, they emphasized the close working relationships between NGOs and various government departments, including units within the Federal Ministry of Health (FMOH) where Research Governance Bodies (RGBs) operate. They suggested that if these departments were not fully knowledgeable about formal research governance, it would be unreasonable to expect NGOs to be entirely compliant with such procedures. Third, they argued that ongoing oversight from government partners ensured that ethical standards were effectively maintained throughout their activities.

One participant illustrated this perspective, stating, "All the parties go together: the [Humanitarian Aid] Commission, UN agencies, the concerned ministries, the governmental counterparts—they form Joint Assessment Missions. When these are established, it represents implicit approval from the governmental agencies and

tacit consent from the communities being assessed. Support comes from all sides to assist these people" (FGD-NGOs1/4).

Several participants also noted that standardized data collection tools, such as questionnaires, had already been reviewed and used in other contexts, further reducing the perceived need for formal ethics approval. One participant explained, "The survey used a standardized [data collection] tool, which has already accounted for ethical considerations and is employed by other NGO missions, so no ethical issues arose during our assessments" (INGO-1).

Finally, NGO and INGO representatives stressed that the absence of formal ethics review did not equate to unethical conduct. They highlighted internal mechanisms and organizational values that guided their work, asserting that ethical standards were upheld even without official committee approval. As one participant remarked, "We follow ethical standards even without knowing there is a Committee on Ethical Standards—we rely on self-monitoring" (FGD-NGOs3/3).

Lack of knowledge about ethics review procedures

Participants consistently identified insufficient awareness of the National Research Ethics Committee (NREC) and the country's research ethics guidelines as a major reason why some studies did not undergo formal ethical review. Both RGB and NGO representatives acknowledged this knowledge gap. RGB officials admitted that limited advocacy and capacity-building efforts may have contributed to this issue, representing a missed opportunity to promote the importance of ethical oversight among stakeholders.

One RGB representative noted, "It is possible that they genuinely are unaware of the NREC. This may be a shortcoming on our part; we did not advocate enough. Greater efforts in advocacy and capacity-building are necessary" (RGB-1).

However, some RGB representatives suggested that NGOs might have deliberately chosen not to pursue ethical approval, reflecting hesitation or a lack of willingness to engage with the formal review process. From this viewpoint, complaints about delays in obtaining approval were seen as unjustified, as the organizations had not initiated the process themselves. This interpretation implies that some NGOs may have used procedural delays as a convenient explanation, highlighting a broader issue of accountability and commitment to ethical standards within certain sectors.

As one official explained, "If NGOs truly intended to submit their studies, they would have done so, allowing the ethical committees to review them. Even if the review takes time, they could then justify delays, but in reality, they never initiate the process. They could request ethical clearance and wait for the response, then cite delays as the reason for proceeding. Yet they do not, and I believe they do not even consider doing so" (RGB-2).

Limitations

This study, while breaking new ground in examining ethical oversight in humanitarian research, has several important limitations that should be considered.

Firstly, the period under study—2004 to 2012—may not fully represent current stakeholder perspectives, as many personnel involved in humanitarian operations have changed since then. Additionally, governance structures and regulations overseeing research may have evolved, meaning that the findings may not fully align with present-day practices in Darfur.

Secondly, the study's context is highly specific to Darfur during the conflict. Although the insights are valuable for understanding research governance in this setting, caution should be exercised when applying them to other humanitarian contexts. The region's unique political, historical, and cultural dynamics may limit the generalizability of the results.

Thirdly, the study had lower participation from International Non-Governmental Organizations (INGOs) compared to national NGOs and government bodies. This disparity may reflect the sensitivity of the topic for INGOs, particularly given the historical expulsion of several INGOs and UN staff by the former Sudanese regime after critical reporting on Darfur [25, 26]. This uneven representation could have affected the range of perspectives captured.

Methodological considerations also warrant attention. Participants may have been influenced by social desirability bias, underreporting ethical lapses or shortcomings. Selection bias is also possible, as those who chose to participate might differ in perspective from those who declined. In Focus Group Discussions (FGDs), participants may have been reluctant to voice opinions that could portray their organizations negatively, and group size may have affected the depth and breadth of discussion.

Finally, there was a delay between the study's completion in 2018 and its publication, due to logistical factors including prioritization of dissemination

methods, timing constraints, and securing publication funding.

Ensuring ethical integrity is fundamental in research, particularly in humanitarian contexts where participants' rights and safety must be protected under challenging and rapidly changing circumstances. In such environments, researchers often face unique dilemmas, balancing the urgency of response with the need to uphold ethical standards.

Humanitarian research is frequently conducted as part of broader aid initiatives, governed by organizational policies and operational protocols that aim to maintain ethical conduct. In these settings, formal ethics review is sometimes perceived as unnecessary. While humanitarian organizations commonly adhere to guiding principles, the interpretation and application of these standards can differ widely across agencies. For instance, values such as humanity, impartiality, and neutrality are embedded in the Humanitarian Principles and the Fundamental Principles of the Red Cross and Red Crescent [27-29], and similar guidance exists in UNHCR frameworks [30] and the SPHERE standards [31]. These differences are influenced by organizational missions, operational strategies, and cultural considerations.

Despite these guiding frameworks, gaps remain in addressing research-specific ethical issues. Existing Codes of Conduct focus primarily on general humanitarian operations and provide limited direction on matters such as autonomy, confidentiality, and privacy for research participants. Additionally, humanitarian coordination mechanisms and cluster meetings often lack expertise in research ethics, limiting their capacity to replace formal ethics oversight.

Drawing on data from stakeholders involved in research in Darfur, our analysis identified five central themes shaping ethical decision-making: inconsistent definitions of research, perceptions of low risk, urgency driven by emergency contexts, prior approval of studies or tools, and insufficient knowledge about ethics review processes. These themes highlight the factors that influence how stakeholders perceive and engage with formal ethical review.

By examining these issues, we highlight the complex interplay between operational pressures and ethical responsibilities in humanitarian research. The findings underscore the importance of fostering ethical awareness, accountability, and proactive engagement within humanitarian organizations. Strengthening these practices can help ensure that research conducted in crisis settings is both ethically sound and operationally effective.

Inconsistent definitions of research

In humanitarian settings, the concept of what constitutes "research" often remains unclear, creating persistent ambiguity across the field. Staff within humanitarian organizations frequently hesitated to describe their work as research, while officials from research governance bodies stressed strict adherence to formal definitions. This difference of perspective highlights the broader challenge of establishing a consistent understanding of research in complex and rapidly evolving humanitarian contexts.

This challenge is reflected in the literature, which documents difficulties in defining research during public health crises [32, 33]. Efforts to separate research from routine public health or operational activities [34] often fall short, as the line between the two can be indistinct.

One important factor is the overlap between operational and research activities. For instance, rapid needs assessments or Joint Assessment Missions primarily aim to gather immediate information for decision-making and program implementation rather than to produce generalizable knowledge. Without clear guidance on how to differentiate research from operational tasks, organizations may classify similar activities inconsistently, leading to confusion and potential ethical gaps. Clarifying these boundaries is essential to uphold ethical standards while ensuring that humanitarian interventions remain responsive and effective under urgent conditions.

Perceptions of low-risk

The variation in how participants perceived risk highlights the subjective nature of evaluating risk in humanitarian research. Representatives from governmental governance bodies generally approached studies with caution, viewing them as inherently carrying potential risk. In contrast, many NGO participants considered humanitarian research activities to be low-risk. This divergence reflects the complexity of assessing risk in humanitarian settings, where priorities and operational considerations differ.

Participants often cited the absence of reported adverse events as evidence that their activities posed minimal risk. However, the lack of documented harm does not automatically indicate the absence of risk. This emphasizes the importance of engaging independent

reviewers who understand the study context but are not directly involved in the research, thereby reducing bias and ensuring a more accurate evaluation of potential risks.

The contrasting perspectives on risk also highlight potential shortcomings in current risk assessment practices and the need for clearer, objective criteria to guide ethical decision-making. Low perceived risk should not be mistaken for no risk, as even studies that appear benign may involve ethical challenges. Implementing objective, context-sensitive risk assessment mechanisms, complemented by expert input, can strengthen ethical oversight. Additionally, continuous monitoring and evaluation throughout the research process are essential to identify and address risks as they emerge, ensuring the protection of participants' rights and well-being.

Perceived urgency due to emergency context

The pressing conditions in Darfur played a major role in shaping participants' perspectives on ethical review procedures. NGOs frequently highlighted time pressures and the urgent nature of their operations as reasons for circumventing formal ethics review. In contrast, officials from governance bodies challenged this rationale, stressing that ethical standards must be maintained even under time-sensitive circumstances.

NGOs' emphasis on prioritizing immediate humanitarian action over formal procedures was countered by governance representatives who pointed to two key considerations. First, the protracted nature of the Darfur conflict and the relative stability of affected populations suggest that not all research activities are truly urgent. Surveys using methods like multistage cluster sampling indicate that populations reside in fairly stable, geographically defined units [35, 36]. While acute events such as hostilities can temporarily heighten humanitarian needs, these situations are often episodic rather than continuous in prolonged conflicts like Darfur. Second, formal ethics review processes are relatively less demanding in terms of time and resources compared to the broader logistical preparations required for humanitarian surveys.

Despite these considerations, there are instances where urgency is unavoidable. Sudden mass displacements or disease outbreaks demand immediate research and intervention [6], and waiting the typical two-month review period could exacerbate harm, increasing morbidity and mortality [37, 38].

Balancing the need for timely response with ethical obligations is therefore critical. Flexible ethical frameworks and expedited review mechanisms can help reconcile these competing demands. Approaches might include pre-approved standard methodologies for rapid assessments or fast-track ethics review procedures, similar to models adopted during public health emergencies [39, 40]. Additionally, ongoing dialogue among stakeholders is essential to create context-sensitive guidelines that address the unique ethical challenges of humanitarian crises while preserving research integrity.

Prior study or tool approval

Relying on informal or tacit approvals, such as coordination with partner ministries, highlights potential gaps in the ethical oversight of humanitarian research. Some stakeholders believe that existing organizational procedures and funding requirements sufficiently safeguard ethical conduct, yet others argue that structured, formal oversight is essential to preserve research integrity.

The absence of detailed guidance specifically addressing research ethics within humanitarian frameworks points to the need for tailored, comprehensive guidelines. Establishing such frameworks requires close cooperation between humanitarian agencies, research governance bodies, and other relevant actors to ensure that the rights, safety, and welfare of participants are rigorously protected throughout the research process.

Lack of knowledge about ethics review procedures

Widespread unfamiliarity with ethics review processes, particularly regarding the role and existence of the National Research Ethics Committee (NREC), represents a major obstacle to conducting research ethically. Some stakeholders view this gap as a consequence of insufficient advocacy and awareness efforts, while others interpret it as a deeper, systemic tendency to overlook or avoid formal ethics procedures in certain sectors.

Overcoming this challenge requires dedicated initiatives to enhance knowledge and understanding of ethical review processes. Building capacity, raising awareness, and fostering a culture that prioritizes ethical research practices are crucial across all organizations involved. Additionally, implementing clear mechanisms for transparency and accountability can help ensure that ethical standards are consistently applied and that researchers remain responsible for adhering to them.

Recommendations

Drawing from our investigation of humanitarian research ethics in Darfur, we provide a series of recommendations to strengthen research governance and ethical oversight during armed conflicts, such as the 2004–2012 Darfur crisis, with the aim of safeguarding participants' well-being, rights, and safety.

Harmonized integrated regulatory oversight

Humanitarian organizations and international stakeholders should engage with governments in regions affected by conflict to create and enforce comprehensive frameworks that regulate research in emergency contexts. This involves formulating policies, laws, and ethical guidelines that clearly specify standards and procedural requirements. Governments should also invest in strengthening regulatory bodies to ensure they can effectively monitor research activities and address ethical challenges. Such oversight not only supports responsible research conduct but also fosters innovation in humanitarian interventions.

Guidelines for emergency research should be developed with input from local communities and based on empirical evidence. These should clearly define what constitutes research in crisis settings, establish criteria for assessing risk, and address ethical considerations specific to conflict zones, taking into account the cultural and moral priorities of affected populations. Collaborative engagement among humanitarian agencies, research institutions, and local actors is essential to integrate ethics into research design from the outset and maintain it throughout implementation.

A practical strategy includes adopting pre-approval mechanisms for commonly used research tools and protocols, allowing studies to proceed efficiently in emergencies while retaining flexibility to adjust tools as circumstances change [41, 42]. Furthermore, harmonizing research oversight with humanitarian governance can create a unified system that balances operational demands with ethical accountability. Such an integrated approach ensures that research in conflict-affected areas is both practical and ethically robust.

Strengthening ethical governance within humanitarian organisations

Humanitarian agencies should actively partner with governments, local communities, and other stakeholders to enhance ethical oversight and governance of research in crisis settings. This includes providing expertise, developing capacity, and allocating resources to strengthen regulatory systems. Promoting the adoption of ethical standards and best practices is essential to ensure accountability, transparency, and the protection of participants' rights and welfare. Building strong collaborative networks creates a foundation that supports ethical conduct throughout research in humanitarian contexts.

Furthermore, ethics education should be embedded in the standard training of humanitarian personnel and researchers operating in conflict zones. This training should emphasize the principles of ethical research, the importance of obtaining formal ethics approvals, and the necessary procedures to ensure compliance with established ethical norms.

Support context-sensitive approaches

Create guidelines and oversight structures that are responsive to the specific challenges of humanitarian emergencies while maintaining ethical integrity. In situations where governments are unable to function effectively, establish temporary ethical oversight mechanisms to ensure that research in conflict-affected regions remains ethically sound. Foster collaboration with international organizations and humanitarian agencies to maintain high ethical standards.

Set up specialized ethics committees with expertise in conflict and emergency contexts to provide guidance and make timely decisions. These committees should implement expedited review procedures that allow research to proceed rapidly while safeguarding participants' rights and welfare. By combining specialized knowledge with efficient, flexible processes, these frameworks can support impartial and prompt decision-making. Streamlined, user-friendly procedures ensure that proposals can be reviewed and approved quickly, minimizing delays without compromising ethical rigor.

Overall, these measures aim to strengthen the ethical governance of research conducted in conflict and emergency settings, protecting participants' rights and ensuring the integrity and quality of research even under challenging circumstances.

Conclusion

This study sought to investigate the ethical dimensions of conducting research in humanitarian settings, using Darfur as a case study. By gathering and analyzing the

perspectives of key stakeholders, the research aimed to illuminate the processes of ethical decision-making and the challenges of governance within humanitarian research.

The analysis identified several prominent themes, including variability in how research is defined, perceptions of low-risk studies, the influence of emergency-driven urgency, reliance on informal or tacit approval processes, and limited awareness of formal ethics review procedures. Participants' differing viewpoints underscored the complexity and nuance involved in ethical decision-making in humanitarian contexts.

These findings carry important implications for both theory and practice. They highlight the necessity of context-specific ethical guidelines and regulatory frameworks that strike a balance between adaptability and rigorous oversight, particularly in resource-limited or conflict-affected settings. Additionally, the insights provide a foundation for future research and contribute to broader discussions on strengthening ethical governance in humanitarian research.

To improve ethical standards in this field, stakeholders should actively promote policy reforms, enhance regulatory and oversight mechanisms, and cultivate a culture of ethical responsibility among research organizations and funding institutions. Through coordinated efforts, it is possible to reinforce ethical practices and maintain high standards of research integrity in complex humanitarian environments.

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Conflict of Interest: None

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Ethics Statement: All the study procedures were performed in accordance with relevant guidelines and regulations, namely the Declaration of Helsinki [21], the National Research Ethics Guidelines of Sudan [22] and was approved by the research ethics committee at the University of Birmingham and the National Research Ethics Committee in Sudan. Informed consent was obtained verbally from all the participants in the focus groups and the interviews with the approval of both research ethics committees in the University of Birmingham and the National Research Ethics Committee in Sudan.

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